Title:	Procedure to Introduce UDI	**Document No.:**	YGD 0305
Effective:	14/03/2023	**Revision:**	2
Revised By:	Jia Qi	**Approved by:**	Punitha

1.0 OBJECTIVE

The objective of this procedure is to introduce a Unique Device Identification (UDI) according to the new Medical Device Regulation (EU) 2017/745.The main provisions related to the establishment of the UDI system are contained in Annex VI of the Medical Device Regulation.

2.0 SCOPE

The procedure applies to all medical devices that produced in YTY Group. Unique Device Identification (UDI) system is intended to provide single, globally harmonized positive identification of YTY medical device products through distribution and use, requiring the label of devices. Various international legislation such as U.S. FDA and MDR requires us to add a Unique Device Identifier (UDI) to the products.

3.0 REFERENCE

I. Medical Device Regulation (2017/745)

II. UDI barcode verification (QA III 100604)

III. European database on medical devices (EUDAMED)

IV. GS1 standard protocol

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4.0 DEFINITION

4.1 **Unique Device Identification (UDI)-** is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market.

4.2 **The Basic UDI-DI** is the primary identifier of a device model. The Basic UDI-DI is the main key in the database and relevant documentation as certificates, declaration of conformity, technical documentation and summary of safety and clinical performance to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics. It is independent and separate from the packaging and labelling of the device and it does not appear on any trade item. It is also known as Global Model Number (GMN).

4.3 **Unique Device Identification -production identifier (UDI-PI)-** contains the expiry date or manufacturing date, if there is no expiry date declared and the lot number. It is also known as Application Identifier (AI).

4.4 **Unique Device Identification -device identifier (UDI-DI)-**is a fixed code specific to a version or model of a device. The UDI-DI must be applied to the medical device label, its packaging and, in some cases, the device itself. It is also known as the Global Trade Item Number (GTIN).

4.5 **GS1 Global Traceability Standard (GTS)-** is a not-for-profit organization to assist organizations and industries in the design and implementation of traceability systems based on the GS1 system of standards.

4.6 **GS1 Barcode-** is a symbol that can be scanned electronically using laser or camera-based systems which is used to They are used to encode information such as product numbers, serial numbers and batch number.

4.7 **GS1-128** is an application standard of the GS1 implementation using Code 128 barcode specification which formerly known as UCC/EAN-128. GS1-128 uses a series of Application Identifiers to include additional data such as best before dates, batch numbers, quantities, weights and many other.

4.8 **Single Registration Number (SRN)** is a code used for unambiguous identification of an economic operator within the EU.

5.0 RESPONSIBILITY

5.1 It is the responsibility of Regulatory Affairs department to get the Basic UDI-DI from GSI and assign UDI-DI to the devices.

5.2 It is the responsibility of Regulatory Affairs department to register the Basic UDI-DI and UDI-DI of the devices in EUDAMED.

5.3 It is the responsibility of IQC department to check the barcode on artwork and packaging.

6.0 PROCEDURE

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6.1 Data that needed related to the codes:

a. SRN

I. Type of economic operator (manufacturer, authorized representative, or importer

II. Company name, address and contact details

III. Name address and contact details of the person responsible for regulatory compliance

b. Basic- UDI-DI

I. Name or identification number of the notified body

II. Type, number and expiry date of the certificate issued by the notified body

III. SRN

IV. Name /address of manufacturer

V. Devices manufactured by another legal or natural person: name, address and contact details of that manufacturer

VI. Member State in which the device is to or has been placed on the market in the Union

VII. Risk class of the device

VIII. Measuring function (y/n)

IX. Implantable (y/n)

X. Reprocessed single-use device (j/n)

XI. Active device (y/n)

XII. Intended to administer / remove medicinal substance (y/n)

XIII. Presence of a medicinal product (y/n) and name of that substance

XIV. Presence of a medicinal product derived from human blood or human plasma (y/n) and name of this substance

XV. Presence of tissues or cells of human origin, or their derivatives (y/n)

XVI. Presence of tissues or cells of animal origin, or their derivatives (y/n)

XVII. * Identification number or link to electronic system of clinical investigations

XVIII. * Specification as to whether the intended purpose of the device is other than a medical purpose

XIX. Status of the device

c. UDI-DI

I. UDI-DI value

II. Quantity per package

III. Basic-UDI-DI

IV. Additional UDI-DI

V. * Reference /catalogue number

VI. * Device model

VII. Direct marking (y/n)

VIII. * Unit of use UDI-PI

IX. Type of UDI-PI

X. Name and address of the manufacturer

XI. SRN

XII. * Name and address of the authorized representative

XIII. Nomenclature Code

XIV. Risk class

XV. * Name/trade name

XVI. * Additional product description

XVII. * Clinical size

XVIII. * Storage /handling condition

XIX. *Medical device nomenclature (CND) code

XX. Single use (y/n)

XXI. * Maximum number of reuses

XXII. Sterile (y/n)

XXIII. Need for sterilization before use (y/n)

XXIV. Containing latex (y/n)

XXV. * Information labelled in accordance with Section 10.4.5 of Annex I

XXVI. * URL for additional information (IFU, etc.)

XXVII. * Critical warnings /contra-indications

XXVIII. Status of the device

XXIX. Systems /procedure pack: UDI-PI

XXX. * Member State of the Placing on the EU Market of the Device

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d. UDI-PI

I. Serial number /lot number

II. Expiry date

III. Manufacturing date, if expiry date is not applicable

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6.2 Overview on the documents on which the new codes like SRN, Basic-UDI-DI and UDI are included:

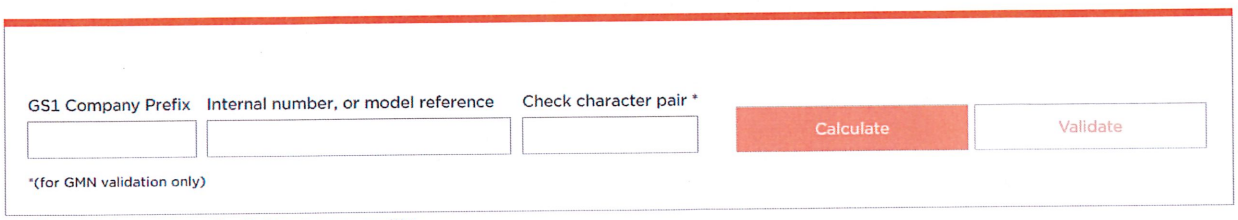
Document	SRN	Basic-UDI-DI	UDI
EU declaration of conformity	X	X	
Conformity assessment	X	X	
Certificate of free sale		X	
Tech. doc. Product description and specification		X	
Tech. doc. Information to be supplied by the manufacturer, up-to-date List			X
Reporting of serious incidents and field safety corrective actions	X		X
EU technical documentation assessment certificate		X	
EU type-examination certificate.		X	
EU product verification certificates		X	
Summary of safety and clinical performance (Class III)	X	X	
Implant card for patients			X

6.3 Steps to compose the Basic UDI-DI

I. The GMN generator is used to generate the GMN based on a GS1 Company Prefix and an internal number, or model reference.

II. The last two characters of the basic UDI-DI are check characters calculated on the previous characters used. The calculator is specifically for a maximum of 25 characters including the check character pair for the Basic UDI-DI. Use our check character calculator above to calculate the check character pair.

6.3.1 GS1 Unique Device Identification (UDI) procedure

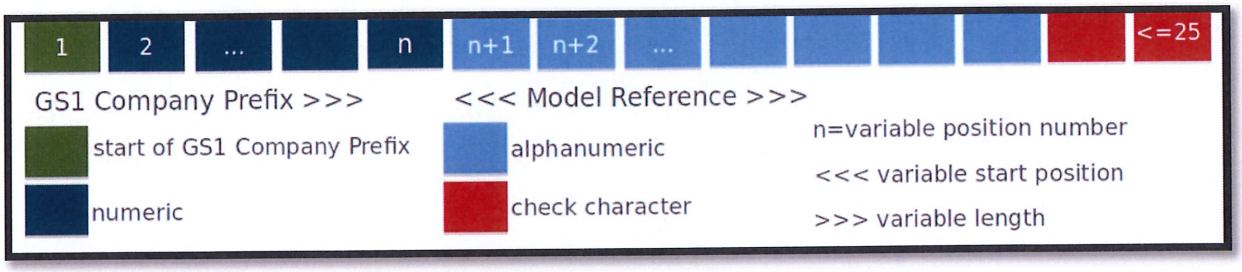


Caution: All characters in the GMN are case sensitive

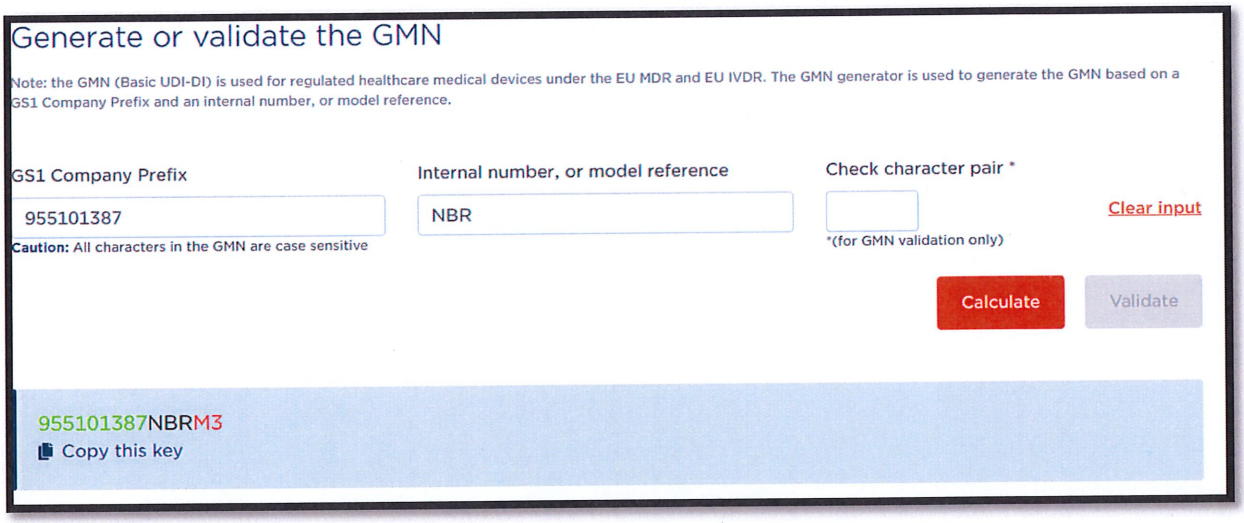
Button definitions as follows:

Calculate: Calculate the check character pair from the GMN (Basic UDI-DI) without check characters by assessing the https://www.gs1.org/services/check-character-calculator.

Validate: Perform checks on the complete GMN (Basic UDI-DI) including check characters.



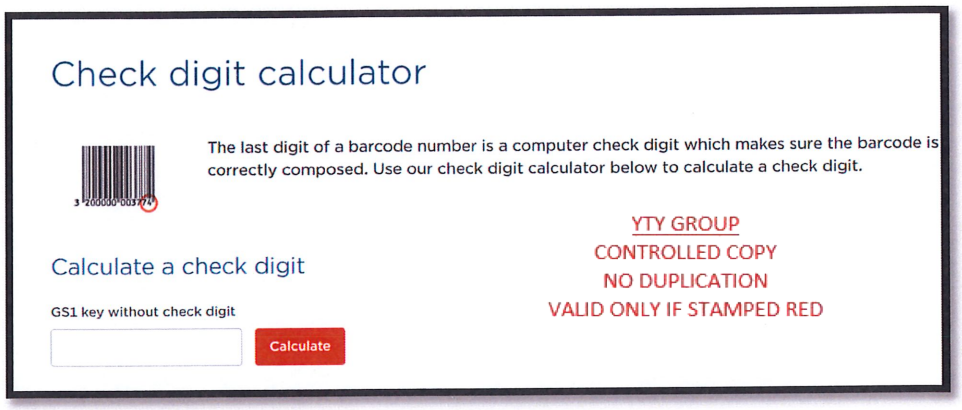
III. For YTY, the Basic UDI-DI is **955101387NBRM3**. The GS1 company prefix is 955101387, Internal model reference is NBR and the check character pair is calculated to get the Basic UDI-DI.



6.4 Steps to compose the UDI-DI

I. Assign a unique identification (Global Trade Item Number - GTIN) by assessing the https://www.gs1.org/services/check-digit-calculator.

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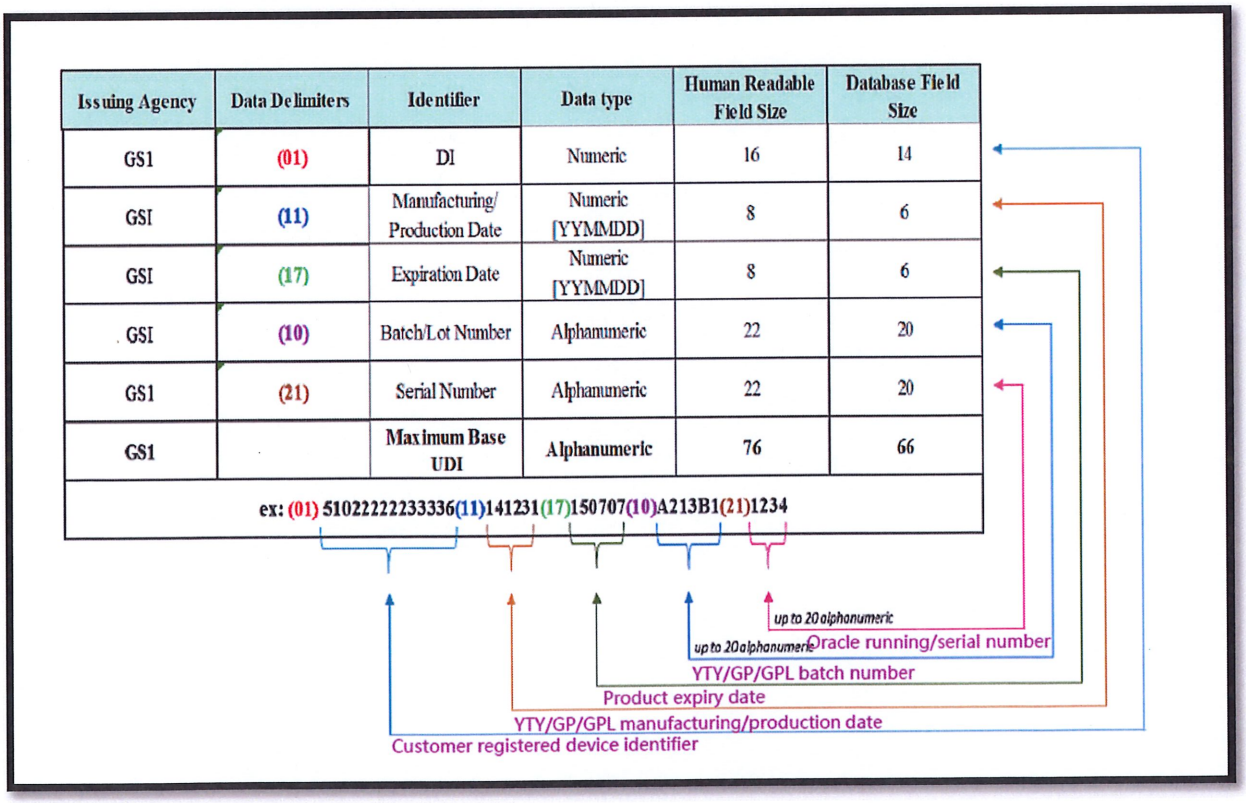


II. Additionally, depending on legislation demands add a batch or lot number, expiration date and/or a serial number, using Application Identifiers.

III. Assign the UDI on products in both text and symbol. Can use a GS1 Data Matrix or a GS1-128.

6.4.1 GS1 Unique Device Identification (UDI) procedure

The GS1 UDI barcode combines the Device Identifier (DI), also known as the GTIN by GS1.org, which would be a static portion to the barcode and then the Production Identifier (PI), which would be a dynamic portion to the barcode, including Application Identifiers such as Serial (AI-21), Lot Number (AI-10) and Expiration Dates (AI-17). The GS1 UDI can be created as a GS1-128 or a GS1 Data Matrix, depending on space allotment on the label.



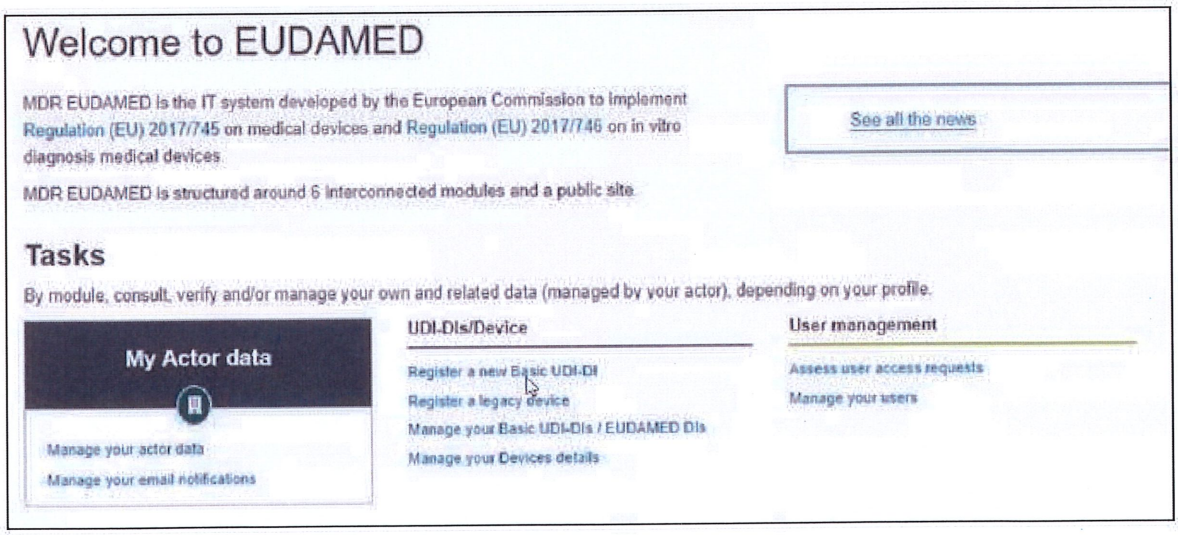
Issuing Agency	Data Delimiters	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	DI	Numeric	16	14
GSI	(11)	Manufacturing/ Production Date	Numeric [YYMMDD]	8	6
GSI	(17)	Expiration Date	Numeric [YYMMDD]	8	6
GSI	(10)	Batch/Lot Number	Alphanumeric	22	20
GS1	(21)	Serial Number	Alphanumeric	22	20
GS1		Maximum Base UDI	Alphanumeric	76	66

The final human readable string for this example:
(01)51022222233336(11)141231(17)150707(10)A213B1(21)1234

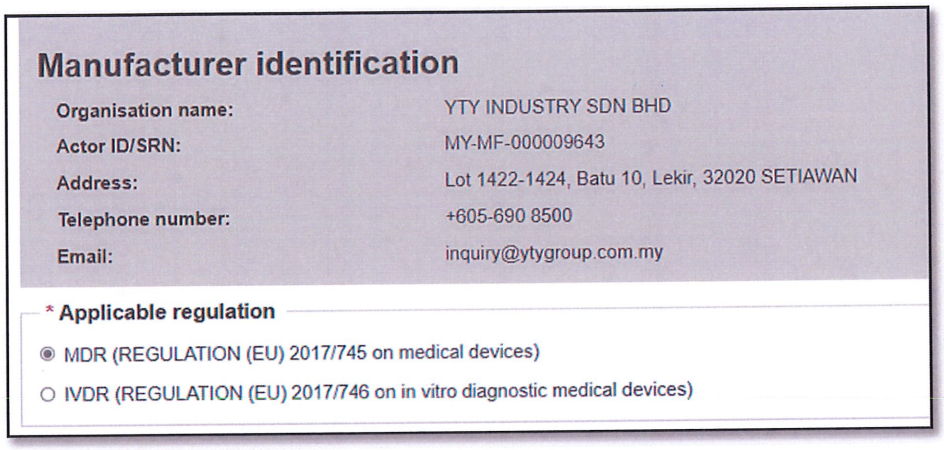


6.5 **Registration of Basic UDI-DI with the first UDI-DI**

6.5.1 Start by clicking on "Register a new Basic UDI-DI".

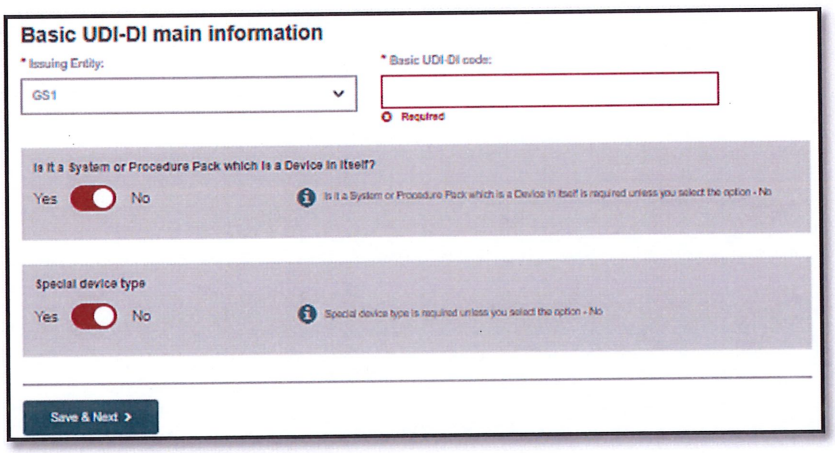


6.5.2 On the next page, start entering the Basic UDI-DI information of the device. Select the applicable legislation for the Basic UDI-DI, choose the MDR (Regulation (EU) 2017/745):



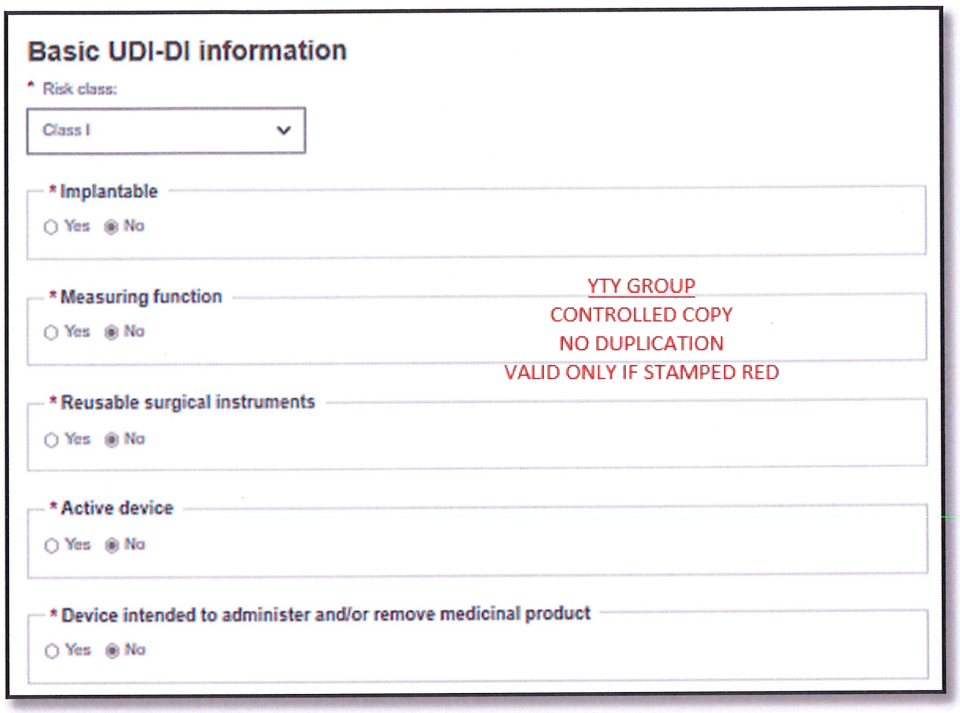
6.5.3 Fill in the Basic UDI-DI identification details and click on "Save & Next".

EUDAMED will perform a validation for the Basic UDI-DI code provided based on the specific format provided by each Issuing Entity as GS1. Ensure that the correct value is provided. Basic UDI-DI duplicates cannot exist in EUDAMED. If the Basic UDI-DI code already exists in EUDAMED for the selected Issuing Entity, need to provide another value.



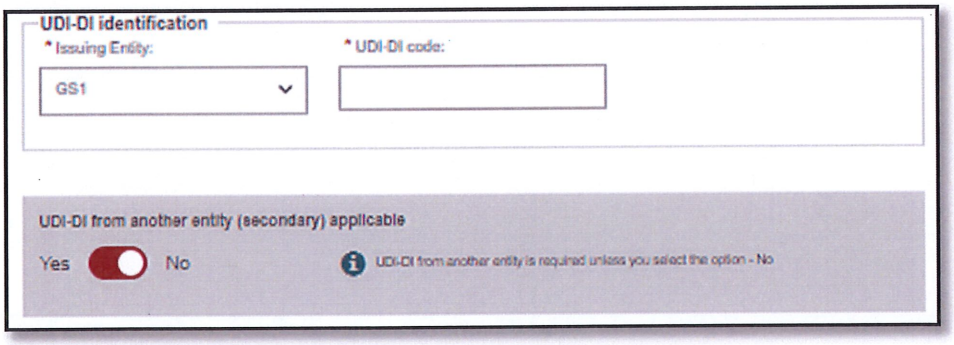
6.5.4 Choose Risk Class and select "YES" or "NO" for each option that follows. Choose "NO" for the implantable, measuring function, reusable surgical instruments, active device and the device intended to administer and/or remove medicinal product.

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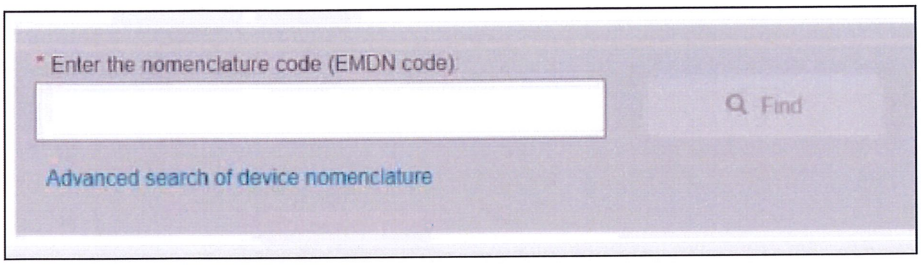
6.5.5 Enter Device model if it is applicable. Then, enter the device name and click on "Save" to save the registration as draft or on "Save & Next" to save it as a draft and continue with the next step.

6.5.6 Select the Issuing Entity and enter the UDI-DI code. Select "No" for UDI-DI from another entity (secondary) applicable.

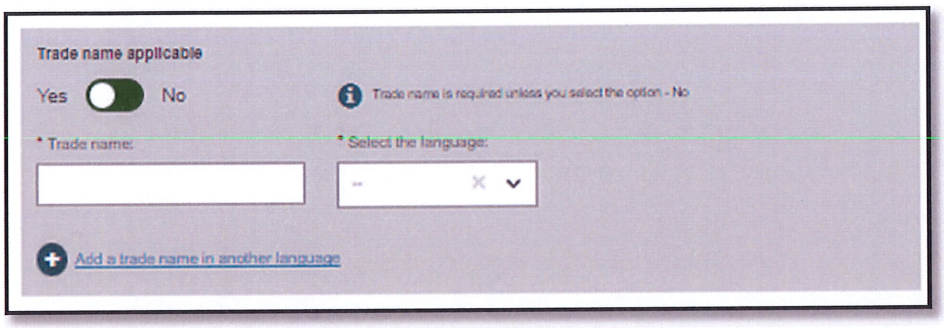


6.5.7 Enter the EMDN code and click on "Find", select the correct one from the list:

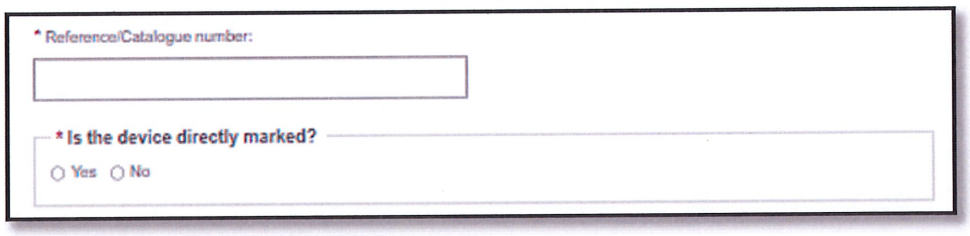
EMDN has been officially chosen as the new European Medical Device Nomenclature. It has a multilevel, tree-like structure of 22 mutually exclusive main anatomical/functional 'categories' and 144 groups. Please note that only lowest-level EMDN codes can be used to describe a device in EUDAMED.



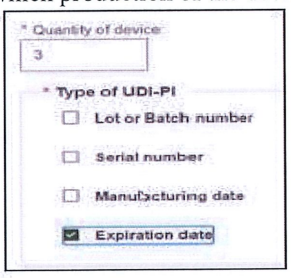
6.5.8 Enter the Trade name if it is applicable and select the language. Otherwise, select "No".



6.5.9 Enter the reference/ catalogue number and select "No" for is the device directly marked. Direct marking means permanently adding the UDI to the device.

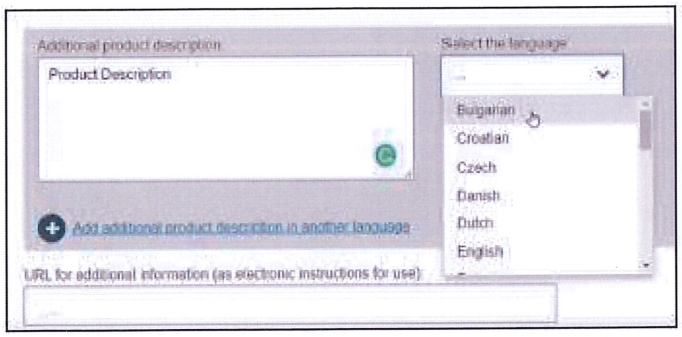


6.5.10 Provide the quantity of devices (the number of devices within a package identified by the specified UDI-DI) and select the type of UDI-PI:UDI-PI describes the manner in which production of the device is controlled.



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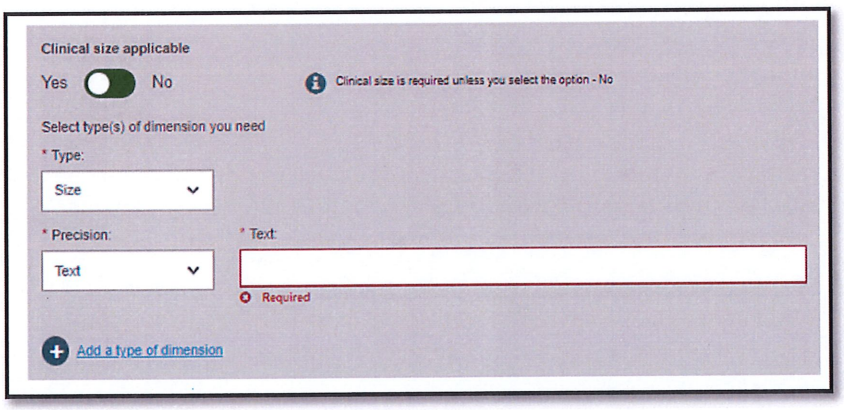
6.5.11 Enter any additional information about the product (any additional information or details about specific features of the device) if applicable, select the language and enter a URL if you have one for additional information online:



6.5.12 Select whether it is on the EU market or not and click on "Save" or "Save & Next":

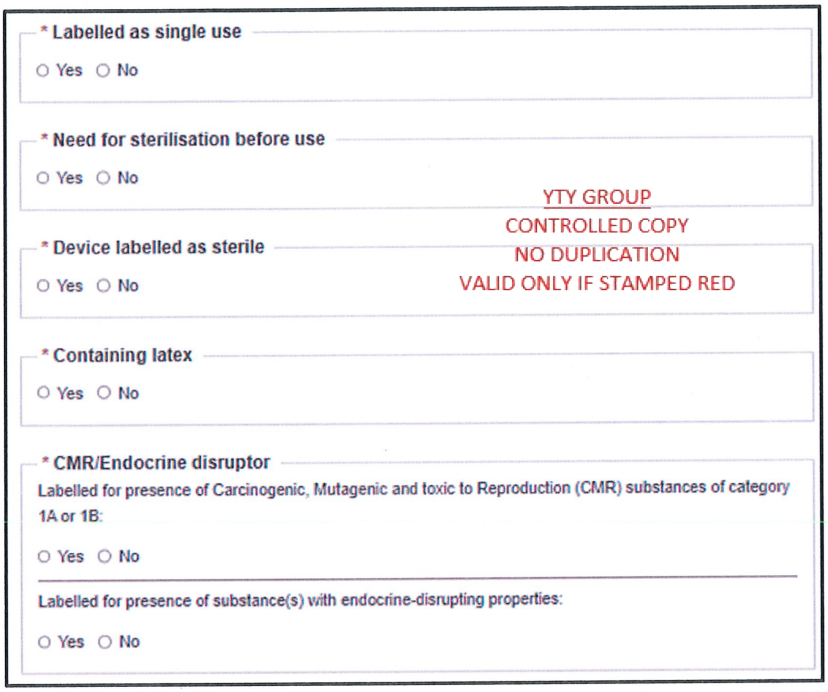


6.5.13 Enter the information for clinical size if applicable. Otherwise, select "No".



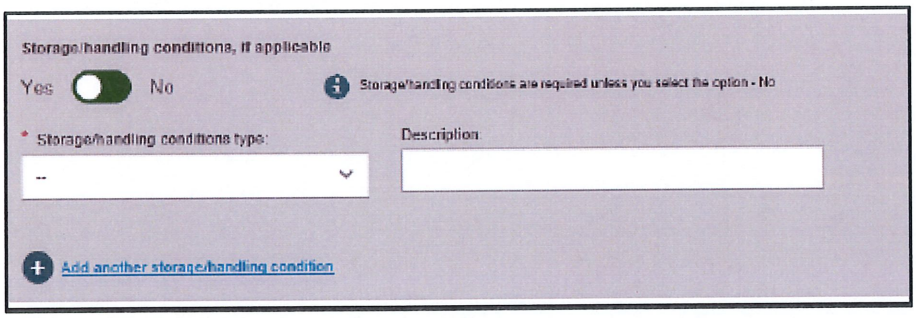
6.5.14 Select "YES" or "NO" for each option that follows.

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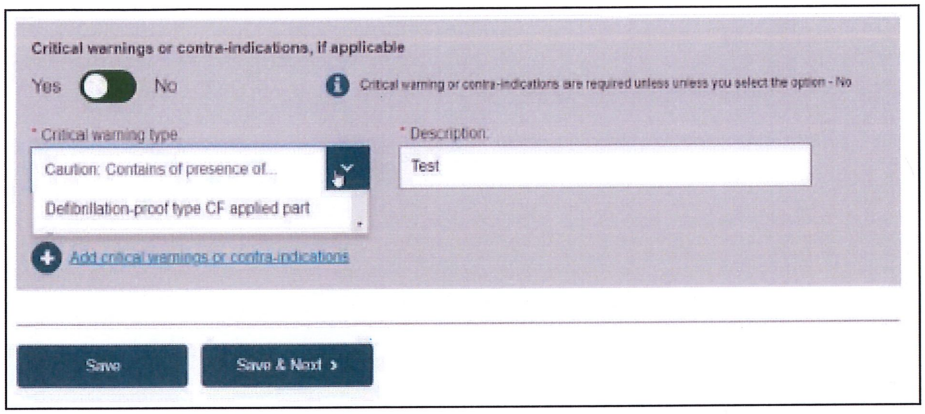


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6.5.15 Select "Yes" or "No" for the Storage or handling conditions, if applicable, and provide the desired values by selecting from the options provided and by entering a description:

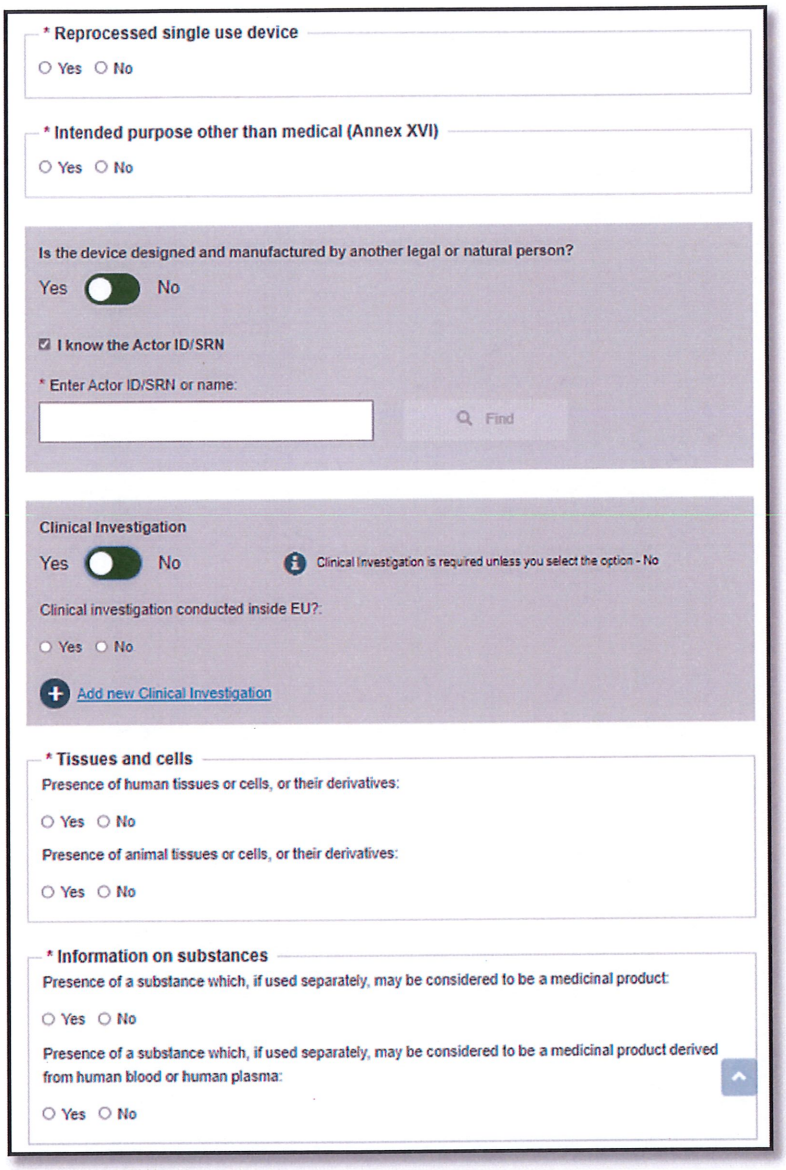


6.5.16 Repeat for Critical warnings or contraindications, and click "Save" or "Save & Next":



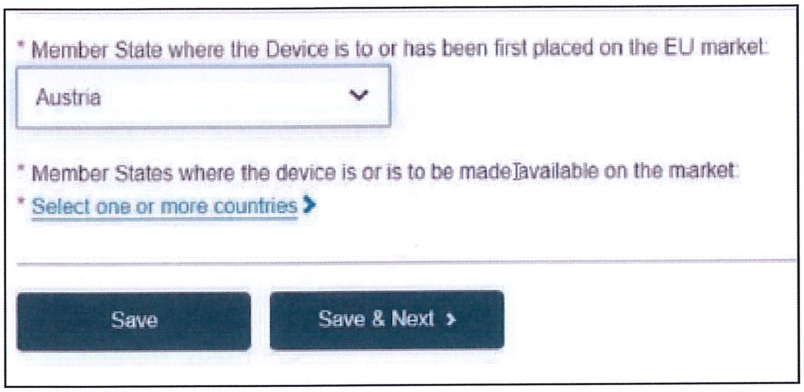
6.5.17 Select "YES" or "NO" for each option that follows.

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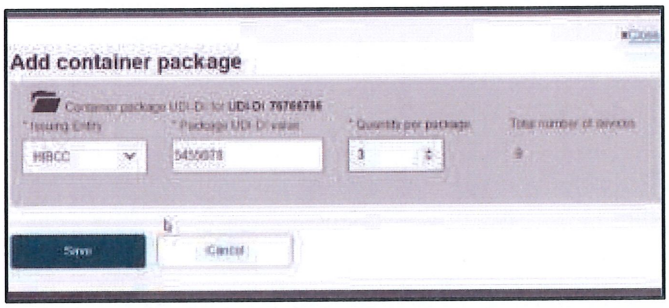


6.5.18 Select a Member State from the dropdown list where the device was or will be first placed on the EU market. Next, choose one or more member states where the device was or will be placed on the market. Click "Save" or "Save & Next":

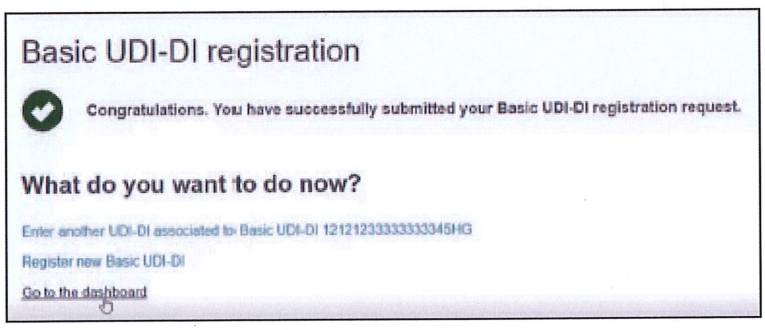
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6.5.19 Click on "Add container package" (Note: this step is not mandatory in order to submit the registration). Container Package information is optional to complete. This page allowsusers to enter the unique UDI-DIs assigned to each package level of the device in order to distinguish between package quantities at each package level, higher level of packaging shall have their own unique UDI. Select the generated information and click on "Submit"



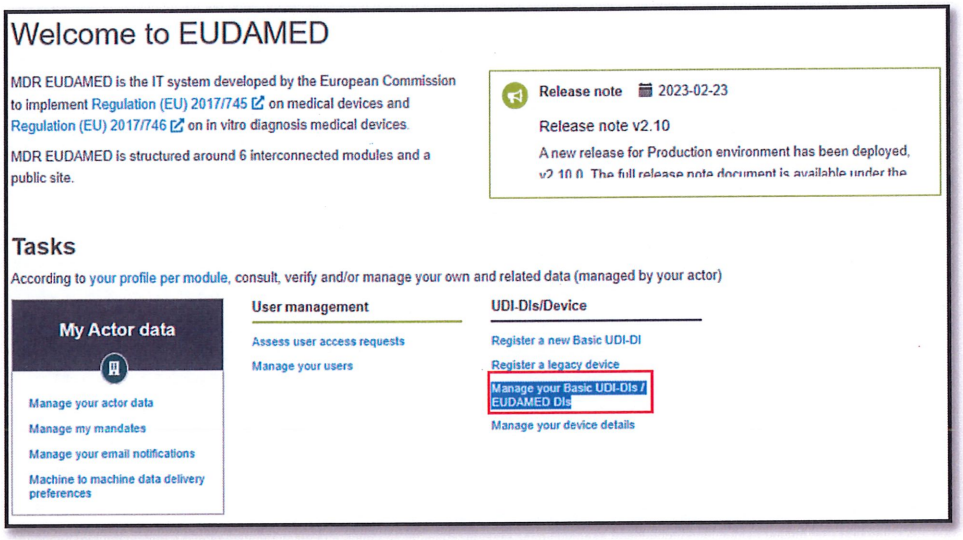
6.5.20 New page will be redirected by saying successfully submitted on the registration.



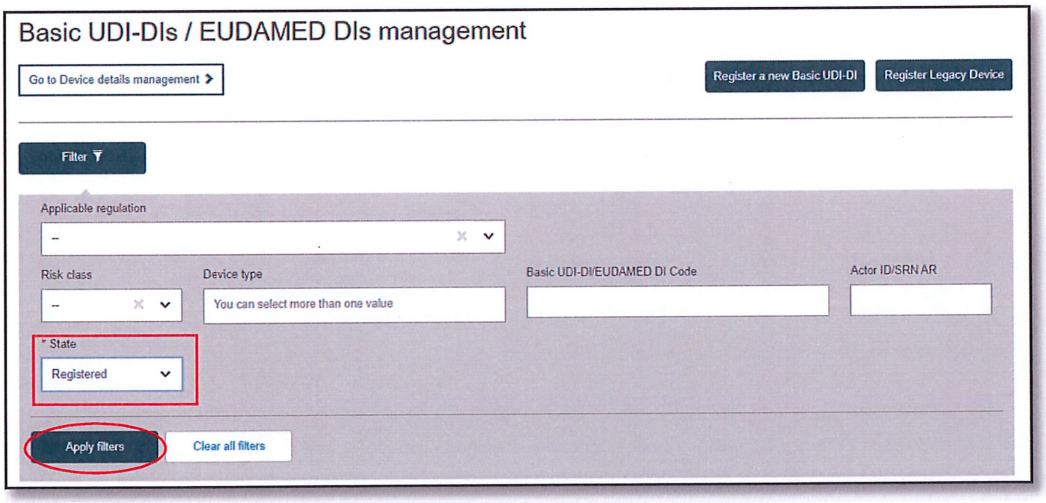
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6.6 Addition of a UDI-DI to existing Basic UDI-DI

6.6.1 In EUDAMED homepage, click on "Manage your Basic UDI-DIs / EUDAMED Dis".

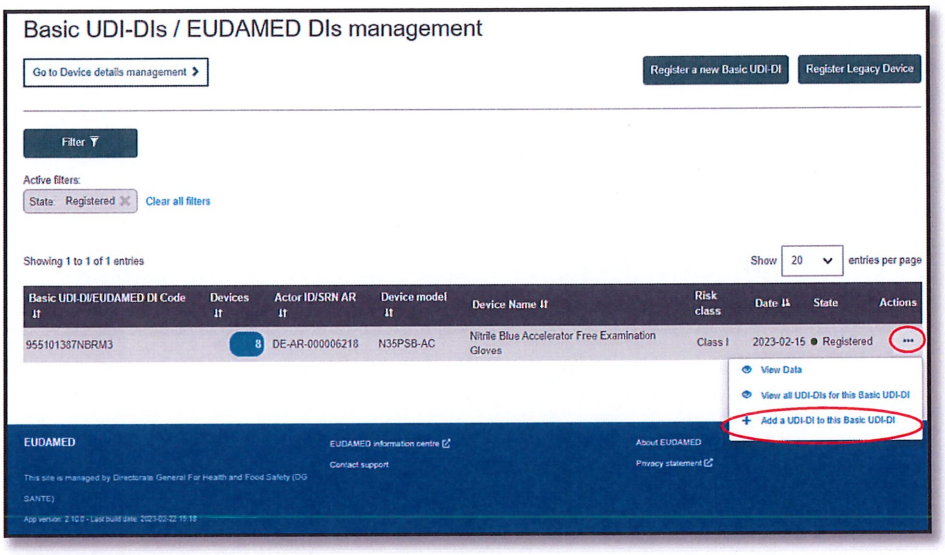


6.6.2 Under the "State" dropdown list, select "Registered" and click on "Apply filters".



6.6.3 Click the icon under "Actions" column for the selected Basic UDI-DI and click on "+ Add a UDI-DI to this Basic UDI-DI".

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6.6.4 Follow steps in Clauses 6.5.6 to 6.5.20.

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Revised By:	Jia Qi	**Approved by:**	Punitha

Reason For Change

Old Revision	*Current Revision*	*Effective Date*	*Page Affected*	*Revision Description*	*Revised By*	*Approved By*
Nil	0	26/07/2021	All	New Procedure	Laxmi	Punitha
0	1	21/06/2022	4,6, 8-12	Add Clause 6.3.1 (III), 6.4 (I) and 6.5	Laxmi	Vengatesh
1	2	14/03/2023	All	Amend Clauses 1.0, 5.0 and 6.5, add Clause 6.6	Jia Qi	Punitha

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